GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:1388
ANSWERED ON:25.07.2017
Regulatory Body for Medical Devices
Chautala Shri Dushyant

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government has any proposal to set up a separate regulatory body for Medical Devices so as to regulate the price and ensure nominal price for medical devices;

(b) if so, the details of the said proposal;

(c) whether it is a fact that there is no regulation for fixing price of imported medical devices in the country which is often higher and not accessible to poor patients; and

(d) if so, the details thereof and the corrective action taken by the Government in this regard ?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) & (b): National Health Policy 2017 recommends establishing a regulatory body for medical devices. However, there is no immediate proposal for separate body for regulation of prices of medical devices.
(c) & (d): Government fixes ceiling price of only those drugs which are included in the National List of Essential Medicines (NLEM) whether domestically manufactured or imported. Drugs in NLEM are consequently put in Schedule-I of the Drugs Price Control Order, 2013. Out of 23 Medical Devices regulated as drugs under the Drugs & Cosmetic Act, only 4 devices viz. cardiac stents, drugs eluting stents, condoms and intra uterine devices have been included in Schedule-I of DPCO, 2013. The remaining 19 medical devices are non-scheduled formulations as per the DPCO, 2013 and manufacturers of these 19 devices are not allowed to increase their prices by more than 10% yearly.
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